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March 9, 2021

VIA CM/ECF
Honorable Thomas I. Vanaskie, Special Master
Stevens & Lee, P.C.
1500 Market Street, East Tower, 18th Floor
Philadelphia, Pennsylvania 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-02875-RBK-JS (D.N.J.)

Dear Judge Vanaskie:

Plaintiffs respectfully submit this letter summarizing the issues in advance of the upcoming March 10, 2021 status conference.

1. **Bellwether Plaintiff Discovery**

The personal injury Plaintiff Fact Sheet ("PFS") in this case is 38 pages long, includes 23 categories of document demands (without subsections), and requests 7 categories of authorizations. CMO 16 containing the personal injury Plaintiff Fact Sheet is attached Exhibit A. Judge Schneider has remarked "[i]t's certainly fulsome, to say the least . . . I guess one of the thoughts that occurred to me is, you know, if this was an individual case, you'd get 25 interrogatories and, like I said, this fact sheet looks fulsome." 7/24/19 Trans. 5:19-6:1 (Ex. B hereto). The final version of the PFS was entered by the Court on October 3, 2019 (CMO 16 Dkt.

249). All personal injury plaintiffs, including those in the bellwether pool, are required to complete a Plaintiff Fact Sheet, to collect documents and authorizations, and to serve them on Defendants within 60 days of the filing of their lawsuit. No other discovery of personal injury plaintiffs has been authorized.

Despite this fulsome production, Defendants now insist that all bellwether plaintiffs must answer an additional, duplicative, and indiscriminate set of Rule 33 and 34 discovery requests on an immediate basis due to the approaching bellwether plaintiff depositions.

As an initial matter, there was never an agreement between the parties that all bellwether cases should be subjected to such discovery—the parties' late December 2020 to early January 2021 email correspondence regarding the bellwether process confirms this fact. Instead, the parties agreed to completing depositions and Defense Fact Sheets for a robust bellwether pool of 28 cases (each side picked 15 cases and two of their picks overlapped – for a total of 28 cases). In addition, the agreement contemplated other discovery including additional depositions that may be taken later and the need to further negotiate deadlines on the Defense Fact Sheets. (The email agreement is attached as Exhibit C). This agreement was silent as to any additional written discovery sought from the plaintiffs. Well after the conclusion of this negotiation, on February 3, 2021, Defendants first made it known they contemplated serving Rule 33 and 34 discovery requests on all bellwether plaintiffs. Had Defendants made it known during the parties' original negotiations that they would be seeking such extensive discovery, Plaintiffs would never have agreed to this large of an initial bellwether pool size. This was never Plaintiffs' expectation at the time the parties reached an agreement on the size of the bellwether pool and Defendants should not be given an opportunity now to freely renegotiate the agreement at Plaintiffs' expense.

With respect to the proposed Rule 33 and 34 discovery, Defendants' insistence on serving the additional requests seems to stem, at least partially, from the Court's allowance of an additional set of document requests to class representatives in the economic, medical monitoring, and TPP class cases. Defendants' Sept. 29, 2020 letter brief to the Court best summarized those additional document requests wherein

> Defendants proposed serving document requests pursuant to FRCP 34 on the consumer and TPP class representatives, as the Plaintiff Fact Sheets the Court previously approved by the Court **do not cover the various categories of information** that are pertinent to the question whether any of the proposed class representatives can satisfy the requirements of Rule 23.

Letter from Seth Goldberg at p.3, Dkt. 582 (emphasis added) (Ex. D hereto). As noted, the Defendants requests were premised on the need for additional categories of documents that were not contemplated in the respective class PFSs—in other words, wholesale categories of documents that the parties had not previously discussed when negotiating their PFSs. Defendants' Sept. 29, 2020 letter brief then went on to state in detail why each additional category of documents was relevant and necessary. *Id.* at p.3-5. Defendants maintained their position at the October 14, 2020 oral argument that

> The wording in the plaintiff fact sheets **is not written to cover any of these kinds of documents** that are on Page 2 of our submission, in particular, are the insurance and deductible information . . . And the information we're seeking now with the Rule 34 requests are truly essential to the questions about ascertainability and their damages calculation, **and this kind of information is not covered in the plaintiff fact sheets**.

10/14/20 Trans. at 26:11-27:10 (Ex. E hereto). Following the submission of Defendants' letter brief and oral arguments, the Court permitted the Defendants to propound additional requests on the above stated basis but cautioned that "**the real issue is whether the requests are appropriate,**

extensive, et cetera, et cetera, **the propriety of each document requests**." *Id*. at 32:7-9 (emphasis added).

In the present case, Plaintiffs are not taking the position that Rule 33 or 34 requests are never allowed. Rather, it is incumbent upon Defendants to show good cause as to why they are entitled to further information about a particular plaintiff that was not already covered by the PFS, and once that good cause has been established, that each request made to a plaintiff is appropriate and narrowly tailored in scope to discover the necessary and relevant information. This is also squarely in line with Judge Schneider's rulings and directives from the July 24, 2019 hearing. Unfortunately, that has not happened here. The Rule 33 and 34 requests Defendants have proposed to serve on all bellwether plaintiffs, are, in most instances, a re-litigation of previous categories of information and documents already contemplated, negotiated, and ruled on in the court-ordered PFS. They are simply attempting to get a 'second bite at the apple', after the issues were extensively litigated, compromised, and ruled upon by Judge Schneider at the July 24, 2019 hearing. A copy of the most recent version of the proposed Rule 33 and 34 requests including Plaintiffs redlines and comments are attached as Exhibit F.

For example, Defendants argued at the July 24, 2019 hearing that plaintiffs should list all healthcare providers and facilities that treated Plaintiff for any reason at section IV(A) and (B) of the PFS, whereas Plaintiffs argued it should be limited to only treatment for hypertension or cancer. Judge Schneider ruled that only disclosure of treatment for hypertension, cancer, and family doctors were relevant (07/24/19 Trans. at 25:6-29:15), and went on to state that

> if there's some type of material medical issue, it would be documented in the family doctor's records and then -- we'll get to the record authorizations in a moment. Same caveat as applies throughout the whole case. Maybe you would say, you don't get it

> in the first instance, but there's good cause, you get it. You know, I'll grant an order granting that request.

07/24/19 Trans. at 26:5-11. In other words, after Defendants have reviewed the medical records of a particular plaintiff, if there is a showing in that plaintiff's medical records as to why disclosure and/or production of documents for another health care provider or facility is relevant, Defendants can make a request for such information. They have not done that here. Instead, Defendants' proposed interrogatories No. 2 and 3 request from all bellwether plaintiffs a listing of all health care providers and facilities who treated the plaintiff for any reason within the past 25 years. This is nothing more than an attempt to broaden the scope—and to re-litigate—what the Court has already ruled on. Moreover, it completely fails to satisfy the Court's requirement for requesting further disclosure, in that there is no particularized showing with respect to a medical record of any particular plaintiff.

Defendants proposed Rule 33 and 34 requests are replete which similar such examples, including interrogatory No. 6 which asks, incredibly, that all bellwether plaintiffs

> State any illnesses, injuries, diseases or medical conditions from which the Plaintiff/Decedent **has ever suffered** not already identified in Plaintiff's Fact Sheet or any amendment thereto. For each, state the date that each such alleged illness, injury, disease or medical condition was first diagnosed and the physician(s) or Health Care Provider(s) who made such diagnosis.

Emphasis added. It would be impractical for Plaintiffs to further brief specific objections to each interrogatory and document request. However, every request sought by Defendants in this new discovery request is duplicative of what has already been litigated, compromised and ruled upon by Judge Schneider at the July 24, 2019 hearing. Plaintiffs are ready to discuss the balance of the requests with the Court at the upcoming March 10, 2021 conference, if necessary. However, Plaintiffs maintain that Defendants must review the information they received from each

individual plaintiff's PFS, medical records, and other documents, to then make a showing as to why additional information from that individual plaintiff is necessary, and to make particularized, narrow requests with respect to that unique plaintiff. Wholesale additional requests as to all bellwether plaintiffs was never contemplated by this Court and should not be allowed now.

2. **Dismissal Procedure for Peripheral Defendants**

   This proposed order was submitted to the Court.

3. **Update on Service of Losartan and Irbesartan Master Complaints**

   At the most recent Case Management Conference, Plaintiffs requested the following:

   (1) That all local defendants waive formal service of process.

   (2) The foreign defendants who were previously in the case as a valsartan defendant waive service.

   (3) The foreign defendants who are new to the case waive service, or in the alternative, that the Court only require each new, foreign defendant to be served once in accordance with the Hague Convention. (As was the case with the valsartan complaints, the service of any complaint will be deemed sufficient.).

   (4) All defendants should be required to accept service of process of all other complaints through MDL Centrality.

Defendants asked the Court two weeks ago for time to confer and form a formal position. Since that date, certain defendants have returned waivers of service, though the defense group has not taken a formal position. Plaintiffs thus renew their ask to the Court so that proceedings are not needlessly delayed by service of process issues. Plaintiffs are attaching an updated log of the status of service upon each defendant as Exhibit G.

4. ZHP's Chinese State Secret Log

ZHP has withheld 91 documents, 88 in their entirety, based on assertion of two Chinese laws that ostensibly require certain categories of information to be maintained on a confidential basis, and not produced. The ZHP state secret logs are attached as Exhibits H & I.[1] Plaintiffs have addressed what appears to be the improper withholding of these documents and have met and conferred with ZHP. ZHP's log fails to satisfy its burden to prove the applicability of the Chinese laws, that the Chinese laws require them to withhold the documents – including every line of 88 out of 91 which is quite unlikely, and that they should be withheld despite the preeminent place of United States law on this question. Thus, Plaintiffs request that the Court order all of the documents to be produced immediately.

In the alternative, ZHP should be required to cure the inadequacies in the log on an expedited basis since this issue has been open since January 1, 2021, when Plaintiffs first challenged the log. The inadequacies include: (1) lack of cast of characters list, identifying each person by name, position, department, and email address – this includes any Chinese government senders or recipients, (2) general references to 7 or 8 sections from the laws with no specificity as to the provisions relied on, (3) inadequate descriptions of the subject matter of the documents with no precision – and in many cases descriptions that bely the privilege assertion (i.e. communications with the Chinese regulatory authority regarding Valsartan quality problems, and the Valsartan project), (4) complete lack of analysis/explanation as to how a specific provision of the purported secrecy laws precludes production of the subject matter of the document/communication, and (5)

[1] Plaintiffs have removed certain columns, containing information such as bates numbers, in order to make the attached PDFs readable. Plaintiffs will send the Excel spreadsheets to the Court with their courtesy copy of this filing via email.

the withholding of entire documents and email chains rather than production with redaction of only the limited information that they argue makes the document confidential. Again, since this information was not provided, ZHP cannot meet its burden. Thus, Plaintiffs' first request is for the Court to rule the burden is not met and order production, as depositions are rolling forward and there is no time for back and forth. If ZHP is given the opportunity to cure, ZHP should be required to address all five listed deficiencies, and in a time frame of five days.

In addition, even if ZHP is allowed to try to cure its inadequate log, during the meet and confer Plaintiffs specifically challenged a number of documents based on the limited descriptions provided and ZHP acknowledged that some of these challenges seemed correct, and others they needed to investigate – those specific documents should be ordered produced immediately regardless of the opportunity to cure the log – as discussed below.

Finally, to the extent the documents are regulatory communications or otherwise fall within the Court's macro discovery order entered on November 25, 2019, requiring production of regulatory communications, ZHP blatantly ignored that Order, failing to even identify those documents as required – and to seek a protective order at that time. (ECF No. 303 ¶ 6, Ex. J hereto). The vague descriptions of the listed documents seem to indicate that ZHP is withholding regulatory communications with the Chinese government in violation of the Court's macro discovery order. That order states that "for each relevant facility the defendants shall produce by December 31, 2019, all regulatory inspection reports, warning letters akin to what the FDA sends, 483- like documents, the responses to these documents, root cause analyses regarding the Valsartan contamination, and documents regarding potential or actual nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated

relevant time period." *Id.* ZHP never informed Plaintiffs or the Court that it would not produce Chinese regulatory documents, or that any such documents existed and were being withheld.

The violation of the core discovery order should also require immediate production of all covered regulatory communications – notwithstanding issues with the assertion of privilege at this point.

Finally, during the meet and confer on March 5, 2021, ZHP disclosed that its attorneys in China have requested a waiver from the Chinese government. This shows that ZHP believes the documents should be produced. Plaintiffs requested production of those communications, which are certainly not privileged. These should be produced immediately, and if any of the communications were oral, the participants, dates, and details should be provided.

Under Federal Rule of Civil Procedure 26(b)(5) and the Court's ESI Order (ECF 127, Ex. K hereto), the party asserting the privilege must provide the opposing party and ultimately the Court with, among other things, "a specific explanation of why each document is privileged or immune from discovery," which "must include a comprehensive presentation of all factual grounds and legal analyses in a non-conclusory fashion." *Pippenger v. Gruppe*, 883 F. Supp. 1201, 1212 (S.D. Ind. 1994); *see also Chao v. Koresko*, Nos. 04-3614, 05-1440, 05-1946, 05-2673, 2005 WL 2521886, at *4 (3d Cir. Oct. 12, 2005) (Ex. L hereto); *Wachtel v. Health Net, Inc.*, 239 F.R.D. 81, 106 (D.N.J. 2006). Moreover, documents containing non-privileged information should be produced with the limited privileged information redacted. *See, e.g.*, *McKee v. PetSmart, Inc.*, 71 F. Supp. 3d 439, 443 (D. Del. 2014) (holding that "to the extent that the PowerPoint presentation may constitute a combination of facts, which are discoverable, and legal conclusions regarding those facts, which are not discoverable, defendant should produce a redacted version of the PowerPoint presentation to plaintiffs."); *Benefitvision Inc. v. Gentiva Health Servs., Inc.*, No. CV

09–473, 2011 WL 3796324, at *2 (E.D.N.Y. May 23, 2011) (holding that "[i]f there are e-mail chains in which Defendants claim privilege over only parts of the e-mail chain, those allegedly privileged e-mails must be redacted and all non-privileged portions must be produced.") (Ex. M hereto); *S.E.C., Inc v. Wyly*, No. 10 Civ. 5760, 2011 WL 3851129, at *5 (S.D.N.Y. June 17, 2011) (same).

When a party has failed to comply with this rule, courts have ordered the party to amend their privilege logs "to allow either plaintiffs or [the c]ourt to evaluate what, if any, claims of privilege [the defendant] may have." *Wultz v. Bank of China Ltd.*, 979 F. Supp. 2d 479, 497 (S.D.N.Y. 2013). **After having this opportunity to amend and failing to comply with the court's order, courts have held that the party "will have waived any claims of privilege over those documents."** *Id.*; *see also Chao*, 2005 WL 2521886, at *4 (**Third Circuit finding that "the District Court acted well within its discretion when it declined to give Respondents a third opportunity to advance their privilege claims"**. The "large volume" and "foreign" or "challenging" nature of the relevant discovery will not excuse compliance with these requirements. *Wultz*, 979 F. Supp. 2d at 497.

Moreover, **the "party relying on foreign law has the burden of showing that such law bars production**." *Schindler Elevator Corp. v. Otis Elevator Co.*, 657 F. Supp. 2d 525, 532 (D.N.J. 2009). Defendants rely on Chinese laws that prohibit the disclosure of "state secrets . . . without the government's permission." *Autodesk, Inc. v. ZWCAD Software Co. Ltd.*, No. 5:14–cv–01409–EJD, 2015 WL 1928184, at *4 (N.D. Cal. Mar. 27, 2015) (Ex. N hereto). For example:

> Article 2 of China's State Secrets Law defines state secrets as **"matters that have a vital bearing on state security and national interests and, as specified by legal procedure, are entrusted to a limited number of people for a given period of time."**

Id. "Article 8 expands this definition to include, among other materials, matters that involve 'national economic and social development' and 'science and technology.'" *Id.* In Defendants' November 23, 2020 agenda letter (ECF 637), ZHP cited a single case in support of enforcing Chinese state secret laws, and that case involved at least seven different Chinese banking laws allegedly baring the discovery. *See Tiffany (NJ) LLC v. Qi Andrew*, 276 F.R.D. 143, 150 (S.D.N.Y. 2011). Thus, the laws have been recognized to be overbroad. Chinese "**laws have broad sweep and can preclude disclosure of a host of nebulously defined categories of information.**" *Munoz v. China Expert Tech., Inc.*, No. No. 07 Civ. 10531, 2011 WL 5346323, at *1 (S.D.N.Y. Nov. 7, 2001) (citing *Richmark Corp. v. Timber Falling Consultants*, 959 F.2d 1468, 1477 (9th Cir.1992)) (Ex. O hereto). Here, the citation to as many as seven or eight different sections of two different laws shows that ZHP is exacerbating an already overbroad law. For example, during the meet and confer ZHP argued that all meeting minutes of meetings with someone from the government are covered, which is clearly overbroad in attempted application.

Given the vague applicability of the state secret laws and the withholding party's burden to show that the laws apply, **Chinese state secret laws "are viewed with some skepticism in U.S. courts."** *Munoz*, 2011 WL 5346323, at *1; *see also Richmark*, 959 F.2d at 1477 (rejecting the withholding party's invocation of Chinese state secret law); *Meggit (Orange Cty.), Inc. v. Nie Yongzhon*, No. SACV 13–0239–DOC, 2015 WL 1809354, *11 (C.D. Cal. Apr. 21, 2015) (same) (Ex. P hereto); *Autodesk*, 2015 WL 1928184, at *4 (same); *Masimo Corp. v. Mindray DS USA, Inc.*, No.: SACV 12-02206, 2014 WL 12589321 (C.D. Cal. May 28, 2014) (same) (Ex. Q hereto).[2]

[2] **Plaintiffs note that none of these cases involved a "privilege log" for Chinese state secrets. Instead, the withholding party moved for a protective order, which the court ultimately denied.** ZHP should have timely done the same here. Instead, ZHP waited over a month after its production was due to inform Plaintiffs and the Court that it had withheld hundreds

In fact, "[t]he Supreme Court has stated that **'[i]t is well settled that [foreign "blocking"] statutes do not deprive an American court of the power to order a party subject to its jurisdiction to produce evidence even though the act of production may violate that statute.'**" *Munoz*, 2011 WL 5346323, at *1 (quoting *Societe Nationale Industrielle Aerospatiale v. United States Dist. Ct., S.D. Iowa*, 482 U.S. 522, 544 n. 29 (2011)). In *Societe Nationale*, the U.S. Supreme Court endorsed the following factors "in deciding whether or not foreign statutes excuse noncompliance with discovery orders:"

(1) "[T]he importance to the investigation or litigation of the documents or other information requested,"

(2) "[T]he degree of specificity of the request,"

(3) "[W]hether the information originated in the United States,"

(4) "[T]he availability of alternative means of securing the information," and

(5) [T]he extent to which noncompliance with the request would undermine important interests of the United States, or compliance with the request would undermine important interests of the state where the information is located."

Richmark, 959 F.2d at 1475 (quoting Restatement (Third) of Foreign Relations Law § 442(1)(c)) (citing *Societe Nationale*, 482 U.S. at 2556 n.28). However, these factors are "not exhaustive." *Id.* Courts have also considered, "the extent and the nature of the hardship that inconsistent enforcement would impose upon the person, ... [and] the extent to which enforcement by action of either state can reasonably be expected to achieve compliance with the rule prescribed by that

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of documents and redacted others, and when it did so, it failed to even provide a reasonable basis, even after having the opportunity to amend its original logs. This fits the ZHP strategy to improperly burden and delay the discovery process.

state." *Id.* (quoting *United States v. Vetco, Inc.*, 691 F.2d 1281, 1288 (9th Cir.), *cert. denied*, 454 U.S. 1098 (1981)). After weighing these factors, the Ninth Circuit affirmed an order requiring the disclosure of information after the Chinese Secrecy Bureau ordered a party "not to disclose or provide the information and documents requested by the United States District Court for the District of Oregon," and warned that the party "shall bear any or all legal consequences should you not comply with this order." *Id.* at 1476, 1478-79.

In *Autodesk*, the court held that:

> ZWSoft also does not show that there is a genuine risk that production of its source code and related documents under the current protective order could subject ZWSoft to **liability** under Chinese state secret and privacy laws. ZWSoft is correct that China has imposed "severe" penalties upon people who have violated its state secrecy or privacy laws. But once again, **ZWSoft's generalized, unsubstantiated claims about Chinese law do not establish that there is a "present danger that application of the PRC blocking statutes" could subject ZWSoft to liability if it produces its source code and related documents in the United States.**

2015 WL 1928184, at *8 (footnotes removed); *see also Masimo*, 2014 WL 12589321, at *3 (noting that the withholding party "has presented no evidence regarding the extent to which the Chinese government enforces its secrecy laws, or the likelihood that any criminal as opposed to only civil or administrative penalties will be issued, making that factor similarly less persuasive in its favor").

Against this backdrop, and despite being given multiple opportunities to correct its inadequacies, ZHP's state secret log does not satisfy ZHP's burden. That is the starting point. On this basis, the documents should be ordered produced in their totality so the parties can move beyond this distraction.

In the alternative, if ZHP is given a final chance to correct the inadequate log, that should happen within five days. As set forth above, Plaintiffs need a cast of characters, so that all people

involved are identified – in some cases it does not even look like a Chinese government member is on the communication, and in the others the government role is unclear. This needs to be remedied. In addition, the generic listing of sections of the cited state secret laws fails to identify the specific provisions relied upon, and the recurrent citation to numerous sections demonstrates a complete lack of precision in identifying a state secret law that specifically applies in each instance. Plaintiffs challenge the efficacy and validity of these generic, overbroad assertions, or their adequacy to support the withholding of the listed documents. The descriptions of the contents and substance of the documents also fail to provide adequate information for Plaintiffs to understand the subject matter of the documents. The descriptions are simply too general and generic to be adequate. And the descriptions also fail to provide sufficient information to support a finding that the substantive contents fall within a particular state secret provision, and that withholding of the document is appropriate. There is simply no analysis or explanation provided, and the conclusory entries are insufficient to meet ZHP's burden.

Also, in every instance but three, entire documents were withheld. ZHP was required to withhold the least amount of information possible, and to the extent portions of a document would not require withholding from Plaintiffs under the law, redaction and production is required. The following examples illustrate the Plaintiffs' analysis of the documents on the log, and we reiterate that Plaintiffs hereby challenge the inclusion of every document on the state secret log, and request immediate production of the entire documents, without redaction.

For example, the first document on the log (from Jucai Ge's custodial file) was apparently created by and solely maintained by Jucai Ge, and is described as, "Summary sheet of information concerning drug marketing licenses provided from Shanghai Municipal Drug Administration." Seven different sections of two sets of state secret laws are cited, with absolutely no analysis or

explanation as to how the vaguely described information in the document is protected by any particular provision, let alone all of them.

The second document (from Sophie Tian's custodial file) is a ZHP internal document, referring to a reply to an opinion regarding the vaguely denoted "valsartan project," and which appears to be a routine regulatory interaction on its face. The added indication that the CDE required ZHP to keep the document confidential does not impact the analysis - in the event the document is truly entitled to be treated as confidential, that would be protected by the protective order. And there is no disclosure of who said this or how or why? Was this a low level clerk? Was it necessary? Finally, the citation to eight different sections of state secret laws is devoid of analysis or explanation as to how the vaguely described information in the document is protected by any particular provision.

The third document (from Lihong Lin and Sophie Tian's custodial files) appears to address a meeting with a Chinese regulatory authority regarding **quality issues with "the product**," which is not defined, and again ZHP cites to eight different sections of the state secret laws without any precision to a particular provision. This is also an entirely internal document.

The fourth document (also from Lihong Lin and Sophie Tian's custodial files), also meeting minutes, is essentially identical to the third document in description. As to both documents, their apparent focus on product quality excludes them from being withheld, on their face, even if a state secret provision did actually apply.

On March 5, 2021, Plaintiffs met and conferred with ZHP and raised the above issues. ZHP agreed to review the entries showing receipt by U.S. employees or use of email addresses from outside of China, acknowledging those could not be privileged. ZHP also advised that lawyers for ZHP in China have asked the appropriate Chinese government entities to agree that

the documents in question can be produced. Plaintiffs then asked ZHP to confirm what lawyers have done so and provide copies of all such communications, and if not in writing to provide a detailed summary of the date, who was involved, and the substance of the request. Plaintiffs anticipate ZHP will claim Plaintiffs did not fully meet and confer. That is untrue. The parties spent a full hour, with at least five members of Plaintiffs' leadership on the call, numerous entries were reviewed and all overarching issues and many examples of specific issues were discussed. ZHP asked Plaintiffs to discuss **every entry** on its logs, which would have taken hours more. Plaintiffs explained that a full hour spent discussing these issues was sufficient to satisfy the obligation to have a substantive discussion as to each type of issue that established the Parties' positions. Plaintiffs asked at the end of the call if there were any documents on the log that ZHP believed raised any unique issues not addressed in the lengthy conference, and ZHP did not identify any. Furthermore, Plaintiffs offered to answer any specific questions via email. Ultimately, ZHP did not ask any such questions.

As explained above, **ZHP actually had an obligation to move for a protective order prior to the deadline for the production of these documents, first with regard to regulatory documents during core discovery, and then as to the rest at the end of November 2020.**

This Court should therefore strike ZHP's entire Chinese state secret log and order the production of the documents in their entirety. *See Wultz*, 979 F. Supp. 2d at 497 (holding that "[i]f [the withholding party] again fails to submit adequate logs, it will have waived any claims of privilege over those documents"); *Chao*, 2005 WL 2521886, at *4 (**Third Circuit finding that "the District Court acted well within its discretion when it declined to give Respondents a third opportunity to advance their privilege claims"**).

Finally, Plaintiffs request an Order prohibiting ZHP from objecting to testimony about the contents of documents other than those found on its log on the basis of Chinese state secrets. This is consistent with Judge Schneider's ruling on this issue when the Chinese state secret issue was first raised by Plaintiffs: "Further discussion of disputes relating to Chinese State Secret and privacy laws and the applicability of the Hague Convention shall await the production of defendants' privilege logs," attached as Exhibit R. At that time, the Court ruled that the state secret issue would be addressed in the context of ZHP's assertion of privilege over documents – recognizing that this assertion would define the outer bounds of any potential objections at the time of depositions.

5. ZHP's Motion to Seal

This issue has been fully briefed and is ripe for the Court's decision. Plaintiffs note that ZHP has repeatedly represented that it needs the Court's decision in order to assess the propriety of its other confidentiality designations, including most deposition exhibits and large swaths of deposition testimony. Plaintiffs disagree because the Court has already issued a decision on this topic and there is no time for a lengthy process to roll along as ZHP would like.

6. Hetero Discovery Issues

Hetero continues to have severe deficiencies in its production. In response to Plaintiffs most recent letter confirming that the supposed curative production is terribly inadequate (*See* Ex. S hereto, listing some but not all of the ongoing issues), Hetero advised that it needs to consult with its ESI vendor. As a result, the depositions scheduled for next week may need to be adjourned again, which is extremely prejudicial to Plaintiffs. The materiality of the documents and information at issue (i.e. central quality control protocols and manuals, disclosure of applications and databases containing testing and other data and information), and the slow pace of Hetero's

actions, is on the threshold of requiring significant sanctions. These materials, and information are central to the proof of the claims, and Plaintiffs reserve the right to request litigation sanctions including an order finding liability. This process must be resolved in short order.

7. Aurobindo Discovery Issues

a. Continued Document Production Issues

In reviewing documents to try to determine if Plaintiffs had the correct custodians as to the Lantech issue, Plaintiffs noticed that many documents were not produced in accordance with the ESI protocol. For example, APL-MDL 2875-0000622-APL has no custodian listed and instead in the custodian field says, "Unspecified Custodian." This issue exists throughout the document production. Plaintiffs asked Aurobindo to correct this issue and have yet to receive a response. It is critically important that Plaintiffs understand where the documents came from so Plaintiffs can understand which custodian can provide testimony as to each document.

Plaintiffs therefore request that the Court order Aurobindo to audit its production and ensure the proper custodian is designated as to each document.

Further, it appears that large numbers of relevant documents have been withheld for undeterminable reasons. By way of example, in looking at Steve Lucas' file, Aurobindo produced 2 emails from 2014 and then no emails until August 27, 2018. Aurobindo's first recall occurred on January 2, 2019, and yet **only 5 of his emails prior to that date were produced.**

Similarly, Jasleen Gupta, has one email from February 3, 2018 (which is the earliest email in her file), there are no emails at all until a single email from May 2019, and then no emails again until July 13, 2018. There is another gap in emails between September 28, 2018 and December 1, 2018. **Aurobindo produced no emails from her custodial file after the recall.**

These issues are common throughout the custodial productions, and the examples provided above are not at all an exhaustive list. Plaintiffs have asked repeatedly why the productions for each custodian are so sparse when these are supposed to be the individuals who were intimately involved with the core issues in this case and have yet to receive an explanation.

Plaintiffs therefore request that the Court compel Aurobindo to confirm all sources of data that were searched as to each custodian (e.g., computer, telephone, file cabinet, etc.).

b. Timing of Production and Updated Custodian List

The following is Plaintiffs' understanding of all custodians for Aurobindo (across all entities):

Original Custodians from 2019 (ECF 328): From AuroLife and Aurobindo USA

- Srinivasulu Ale
- Sudhir Bheeminemi
- Daniel Burns
- Krishna Reddy Chada
- Bhadresh Doshi
- Prasad Gorijavolu
- Jasleen Gupta
- Jeffrey Jackowski
- Blessy Johns
- Venkata Kota
- Steve Lucas
- Sandra Martinez
- David Palew
- Arpit Patel
- Milind Shirshikar

Newly Added Custodians in 2021

During the last Case Management Conference, the Court ordered Aurobindo to complete production of these custodial files in their entirety by mid-March. Aurobindo contacted Plaintiffs last week and informed Plaintiffs that it will have difficulty meeting that deadline. Aurobindo

indicated it was willing to produce 4 custodial files by March 12, and an additional four files by April 1 as follows:[3]

- Sanjay Singh (Sr. VP of Operations - North America) **- Aurobindo will produce by April 1**
- Mr. Mallikarjun (Unit 7 Operations Head)
- Mr. Pravatkumar Tripathy (Unit 7 Quality In-charge) **- Aurobindo will produce by March 12**
- Mr. Sarath kumar Kamavarapu (API Unit XI Quality In-charge) **- Aurobindo will produce by March 12**
- Mr. M V Rama Krishna (API Unit XI Operations Head) **- Aurobindo will produce by April 1**
- Mr. Hanumanthu Penchalaiah (Global Pharmacovigilance Head)
- Mahesh B. Shinde (Quality Head - Unit 7) **- Aurobindo will produce by March 12**
- Dr. Srinivas K Rama (Quality Head - Unit 11) **- Aurobindo will produce by March 12**
- MV Subba Raju (Manufacturing Department) **- Aurobindo will produce by April 1**
- T Rajasekhar Reddy (Manufacturing Department)
- P. Sateesh Kumar (Manufacturing, Science, and Technology)
- GV Srinivasa Sudhakar Varma (Engineering & Utility)
- N Somasundaram (Quality Control)
- A Srinivasa Reddy (Warehouse)
- R Srinivasa Rao (Quality Assurance)
- A Srikanth (Quality Assurance)
- Mr. Kesava Reddy (VP Outsourcing)
- Mr. Ashok Reddy (Assistant General Manager of Corporate QA)
- Mr. Nagaraju (don't have full name) (Deputy Manager of Quality Assurance)

This means that more than 10 custodial files do not have an anticipated production date.

Aurobindo also indicated that the remaining custodial files were collected by the company, copied onto hard drives, and then were mailed to its counsel and are now stuck in customs. Aurobindo's counsel indicated that this would delay its production of these files until it

[3] There is one additional custodian Aurobindo volunteered to produce by April 1, but Plaintiffs could not find a custodian with the name provided by Aurobindo and Aurobindo's counsel has not yet responded to Plaintiffs' request for clarification.

received further news on the tracking for these packages. Aurobindo's counsel was asked if copies of the hard drive were made before the data was mailed out. Aurobindo confirmed that copies existed at the company.

Plaintiffs indicated during the meet and confer that Plaintiffs are willing to allow Aurobindo to produce some information through April 9, but that Plaintiffs would not agree to delay document productions beyond that date, and that Plaintiffs need to be able to determine which custodians' files are prioritized, in light of the upcoming depositions. To the extent Aurobindo's review is delayed as a result of the company's decision to transfer the files to its attorneys via mail (rather than FTP, which has been the industry standard for a long time now), Aurobindo should not receive further extensions from the Court as a result of a problem of its own making, particularly when the Court previously ordered Aurobindo to produce documents by a date certain.

Plaintiffs therefore request that the Court amend its prior (forthcoming written) order as follows: Aurobindo may complete production of all documents (including those discussed in other portions of this agenda letter) by April 9 with the following parameters:

1. The custodial files of all quality custodians must be produced by the March 15 deadline.
2. Aurobindo will produce the four custodial files noted above by April 1, as well as the custodial files designated as a result of the custodian's proximity to the Lantech issues discussed with the Court as the February Case Management Conference (as discussed more fully below).
3. All remaining custodial files can be produced on a rolling basis on or before April 9. If, as of April 9, there are documents Aurobindo has not reviewed, all unreviewed documents should be produced, subject to claw backs for privilege or work product.

c. Lantech Custodians

At the February Case Management Conference, the Court approved Plaintiffs' request that Aurobindo add additional custodial files to cover the following topics from our prior agenda letter:

1. Contracting with Lantech;
2. Conducting due diligence on Lantech in terms of quality and cGMP compliance;

3. Providing Lantech with specifications for the use, recovery, recycling, and cleaning of the solvents used in the manufacture of Aurobindo's VCDs; and
4. Investigating any cGMP, contamination, or NDMA issues with Lantech.

On March 4, 2021, Aurobindo's counsel provided the three names listed below. After searching through the documents, Plaintiffs were able to find very little on these three individuals, particularly Mr. Kasava Reddy and Mr. Nagaraju (as detailed below). Accordingly, Plaintiffs requested additional information as to why Aurobindo selected each custodian and which topics from the agenda letter are covered by each, and for what time period. To date, Plaintiffs have not received a response. Plaintiffs therefore request that the Court compel Aurobindo to provide Plaintiffs with this information now to ensure the proper custodians have been selected.

Plaintiffs have provided what little information they could find on each custodian below for context:

- **Mr. Kesava Reddy (VP Outsourcing) -** His name appears in only 2 documents produced to date, and it is therefore impossible to determine what he does or whether he is relevant.
- **Mr. Ashok Reddy (Assistant General Manager of Corporate QA) -** Plaintiffs agree to this custodian, so long as this is the same person being referenced in APL-MDL 2875-0031674-APL-MDL 2875-0031767 at page 1 of the document.
- **Mr. Nagaraju (full name not provided by Aurobindo) (Deputy Manager of Quality Assurance) -** Plaintiffs are concerned that this is not a relevant custodian. In APL-MDL 2875-0026486-APL, Mr. Nagaraju is referred to as the Quality Assistance person for Unit XVI, which to Plaintiffs' knowledge did not make valsartan.

In light of the above, Plaintiffs are concerned that the custodians above are either not the right people and/or are insufficient to cover the issues Plaintiffs requested. While Plaintiffs only have the benefit of just over 600 documents from Aurobindo Pharma Ltd. at this time, based upon the review of these documents, Plaintiffs proposed the addition of Dr. A. Ram Mohan Rao (Chief Quality Officer). Dr. Rao signed Aurobindo's response letter to the FDA's 483 notice and is also

listed as point person relating to the recall and participated in meetings with the FDA. Because Aurobindo's counsel has not responded to this request, Plaintiffs request that the Court order Aurobindo to add Dr. Rao as a custodian.

d. Searches and Production of Non-Custodial Sources

Plaintiffs have asked Aurobindo multiple times for a list of all non-custodial sources it searched in responding to Plaintiffs Requests for Production. Because Plaintiffs have not received this after asking repeatedly, we will be asking the Court to order an officer of the company to provide an affidavit specifying which noncustodial sources were searched, particularly as to Aurobindo Pharma Ltd. Aurobindo Pharma Ltd. has made exactly one production throughout the entirety of this case (on June 30, 2020). According to Aurobindo's production log, the only sources of data for this production were regulatory files. This does not even begin to cover the scope of the information required by the Court-approved Rule 34 requests. For example, standard operating procedures are generally non-custodial documents. Aurobindo did just produce standard operating procedures and provided Plaintiffs with a certification of compliance, but not a single document in that most recent production came with an APL bates number, indicating that not a single operating procedure from Aurobindo Pharma Ltd. was produced.

Plaintiffs therefore request that Court compel Aurobindo to do the following:

(1) Provide Plaintiffs with a comprehensive list of all non-custodial sources it searched (from all Aurobindo entities) and collected documents from in responding to Plaintiffs' Rule 34 requests;
(2) Supplement its standard operating procedure production with standard operating procedures which are responsive to Plaintiffs' Rule 34 requests; and
(3) Supplement its document production with noncustodial data that is responsive to Plaintiffs' Rule 34 requests.

e. ToxRox and Meridan Privilege Log

Plaintiffs served third-party subpoenas on ToxRox (a toxicology consultant) and Meridan (a cGMP consultant), and Plaintiffs and Aurobindo were able to come to an agreement that Aurobindo would produce these documents on behalf of the two entities, subject to their ability to withhold documents for privilege and work product. Aurobindo produced certain documents to Plaintiffs in February 2021 with a privilege log.[4] (Ex. W hereto). In reviewing the log, Plaintiffs are at a loss for how Aurobindo can claim either work-product protection or privilege as to documents generated by or sent to a third party.

Aurobindo seeks work-product protection for various documents listed in its privilege log related to ToxRox and Meridan,[5] but none of the documents are entitled to work-product protection because they were not prepared in anticipation of litigation, which is a prerequisite for work-product protection.

Magistrate Judge Schneider authored an opinion in *In re Riddell Concussion Reduction Litig.*, 2016 WL 7108455 (D.N.J. Dec. 5, 2016) (Ex. T hereto), that is dispositive[6] of the present issues before the Court. In *In re Riddell*, Judge Schneider explained that the "burden of proving that a document is protected rests with the party asserting the work-product doctrine." *Id.* at *6. As part of Aurobindo's burden, it must "demonstrate the precise manner in which a document is protected." *Id.* "Blanket assertions do not suffice." *Id.* "For materials to be eligible under this

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[4] The initial production of these documents was made improperly, and Aurobindo subsequently produced them in a format allowing them to be loaded into Plaintiffs' document review platform on March 4, 2021.

[5] ToxRox and Meridan are third-party consultants used by Aurobindo.

[6] Indeed, during the January 5, 2021 conference, Judge Schneider pointed the parties to the *Riddell* decision as precedent concerning the issues now raised before the Court. *See* Transcript of Telephonic Status Conference with Oral Argument and Rulings, 49:10-19 (the "Transcript") (Ex. U hereto).

protection, it must be reasonably clear based on the surrounding facts and the nature of the materials that they were in fact prepared or obtained because of pending or anticipated litigation." *Reich v. Hercules, Inc.*, 857 F. Supp. 367, 373 (D.N.J. 1994). "Thus, a party seeking to invoke the work-product doctrine must prove at least two elements. First, that a document was prepared because of reasonably anticipated litigation. Second, that **the material was prepared because of the prospect of litigation and for no other purpose**." *In re Riddell*, 2016 WL 7108455, at *6 (emphasis added). As it relates to the first element, "[t]he mere involvement of an attorney does not, in itself, evidence that a document was prepared in anticipation of litigation." *Id.* at 7. Here, Aurobindo's designations do not satisfy either element.

The bulk of Aurobindo's work product designations (with some exceptions noted below), fall into two categories. The first is "work product - draft document, which includes strategy proposed by consultant in response to FDA warning letter,"[7] and the second is "work product - draft document, which includes strategy proposed by consultant in response to FDA 483 letter."[8]

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[7] These include entries 101-105, and 113, Bates Nos.: Auro-MDL 2875-0109718, Auro-MDL 2875-0109719, Auro-MDL 2875-0109720, Auro-MDL 2875-0109721, Auro-MDL 2875-0109722, Auro-MDL 2875-0109744-45. Aurobindo's privilege log is attached hereto as Exhibit B.

[8] These include entries 106-111, 114-147, 149-154, and 156-159, Bates Nos.: Auro-MDL 2875-0109738, Auro-MDL 2875-0109739, Auro-MDL 2875-0109740, Auro-MDL 2875-0109741, Auro-MDL 2875-0109742, Auro-MDL 2875-0109743, Auro-MDL 2875-0109746, Auro-MDL 2875-0109747, Auro-MDL 2875-0109748, Auro-MDL 2875-0109749, Auro-MDL 2875-0109750, Auro-MDL 2875-0109751, Auro-MDL 2875-0109752, Auro-MDL 2875-0109753, Auro-MDL 2875-0109754, Auro-MDL 2875-0109755, Auro-MDL 2875-0109756, Auro-MDL 2875-0109757, Auro-MDL 2875-0109848, Auro-MDL 2875-0109849-62, Auro-MDL 2875-0109863-70, Auro-MDL 2875-0109871-73, Auro-MDL 2875-0109874-79, Auro-MDL 2875-0109880, Auro-MDL 2875-0109881, Auro-MDL 2875-0109882, Auro-MDL 2875-0109883, Auro-MDL 2875-0109884, Auro-MDL 2875-0109885, Auro-MDL 2875-0109886, Auro-MDL 2875-0109887, Auro-MDL 2875-0109888-89, Auro-MDL 2875-0109890, Auro-MDL 2875-0109891, Auro-MDL 2875-0109892, Auro-MDL 2875-0109893, Auro-MDL 2875-0109894, Auro-MDL 2875-0109895, Auro-MDL 2875-0109896, Auro-MDL 2875-0109900, Auro-MDL 2875-0109901, Auro-MDL 2875-0109902-07, Auro-MDL 2875-0109908, Auro-

Because responses to warning letters and FDA 483 letters are ordinary aspects of the regulatory process that would have occurred regardless of whether this litigation existed or not, they are not entitled to work product protection. Said another way, the documents in question were prepared for a purpose other than just litigation. *See In re New York Renu With Moistureloc Prod. Liab. Litig.*, 2009 WL 2842745, at *2 (D.S.C. July 6, 2009) (denying work product protection where outside counsel for the defendant retained a consultant in response to FDA inspection and resulting warning letter even though "at that time, it was certainly foreseeable that lawsuits might be brought by the FDA and by Bausch & Lomb consumers as well" because the "[d]efendant has not satisfied its burden of proving that [the consultant] prepared the report solely in anticipation of litigation") (Ex. V hereto); *In re Riddell*, 2016 WL 7108455, at *7 ("Riddell's work-product assertion is rejected because there is no evidence its documents were prepared because of impending litigation. It is true that many of Riddell's documents were prepared because of Congressional inquiries into concussions. However, no evidence exists to show this was likely to lead to litigation. As noted, the mere 'remote prospect' or 'inchoate possibility' of litigation does not satisfy the work-product doctrine."). As Judge Schneider stated, the work product question is "a relatively easy issue. Was the primary purpose of the preparation of the documents a business purpose responding to the FDA or preparing for litigation?" *See* Transcript at 49:20-23 (Ex. U hereto). Here, the answer is that Aurobindo prepared these documents for business purposes to respond to the FDA. Therefore, Aurobindo is not entitled to work-product protection for the challenged documents.

There are other miscellaneous entries on Aurobindo's privilege log that are also not entitled to work-product protection. For example, entry number 112, Bates No. Auro-MDL 2875-

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MDL 2875-0109909-10, Auro-MDL 2875-0109911, Auro-MDL 2875-0109913, Auro-MDL 2875-0109914, Auro-MDL 2875-0109915, Auro-MDL 2875-0109916. *See* Ex. B.

0109744-45 simply states "work product" in the privilege description section and "raghu" as the author (who may or may not be an attorney). This sparse designation does not satisfy either element set forth in *Riddell*, and therefore should be produced. The same is true for entry 148, Bates No. Auro-MDL 2875-0109898, which contains a privilege description that states "work product – sent 6/26/2019" and an author listed as "APL UNIT6." This entry similarly does not meet either element of *Riddell*, and therefore should be produced. The same is true for entry 155, Bates No. Auro-MDL 2875-0109912, and entry 160, Bates No. Auro-MDL 2875-0109917.

Plaintiffs therefore request that all documents logged on Aurobindo's privilege log relating to Meridan and ToxRox be deemed improper. Plaintiffs further request that Aurobindo be compelled to produce these documents within 5 days.

8. Mylan Discovery Issues

Plaintiffs are currently in the midst of deposing Mylan's first corporate designee, Derek Glover, who Mylan has designated for over half of their 30(b)(6) topics (including key topics such as the nitrosamine contamination, and testing). The deposition began on Tuesday March 9, 2021 and will continue on Thursday March 11, 2021 and Friday March 12, 2021.

The weekend before this deposition began, at 1:16amET on March 6, 2021, Mylan made a new production of over 35,000 documents from the custodial files of over 60 custodians. From these 35,000 documents, Mylan proceeded to withhold, as "non-responsive" over 20,000 documents. These "non-responsive" documents include documents with the following filenames:

- "Valsartan – Nitrosamines Data.xls"
- "Service Provider (Lantech).pdf"[9]
- NDMA-NDEA.xlsx

[9] Lantech is one of Mylan's solvent recovery vendors for Valsartan sold in the United States. Mylan identified the use of recovered solvents as being a root cause for their contamination.

- Evaluation report regarding NDMA.PDF
- Valsartan @ NDMA (final).docx
- Lantech 2011-2019.xlsx
- Lantech Valsatran Pharma status.xls
- Lantech VLN & VST 2.pdf
- Lantech.Rec TBTC & Rec O-Xyl Valsartan II.Rev.03.pdf
- Lantech.Valsartan (VLN) II from Crude Valsartan (VLN) II RE.Rev.03.pdf
- Appendix- 1 Warning letter.pdf
- O-Xylene failures in VST-II Report (Ref PR#942929 948081 948089).pdf

Defendants' practice of improperly withholding attachments to emails on the basis of being allegedly "non-responsive" is not a new one before this Court. Plaintiffs first raised the practice with the Court in December of 2020. At that time, the Court requested that the parties meet-and-confer on the issue. Mylan then committed to conduct a review of their withheld documents and proceeding to make a re-production of responsive documents that had been previously withheld as non-responsive." However, with this new production, it is obvious that there are, yet again, highly relevant documents which are being withheld on the grounds of being "non-responsive."

On Saturday March 6, after receiving the production at 1:16amET, (and while in the process of preparing for a deposition), Plaintiffs proceeded to identify, with particularity, all withheld documents in Mylan's latest production that Plaintiffs believe are responsive and should have been produced (such as the above-delineated examples). Despite this being a repeated issue that has carried over from 2020, Mylan is asking to yet again delay the process by requiring the Parties to meet and confer after the Mr. Glover's 30(b)(6) deposition. Given the pressing nature of the upcoming depositions, Plaintiffs ask the Court should order that Mylan should produce all documents listed by Plaintiffs or provide a particularized justification for why that facially relevant document is non-responsive. Having such justifications will then make a subsequent conferral a more fruitful process.

9. Retailer and Wholesaler Discovery Issues

Plaintiffs have reached an apparent impasse over Plaintiffs' draft second set of document requests and deposition notices directed to Wholesaler and Retail Pharmacy Defendants, which Plaintiffs served on December 8, 2020. After months of delay, both sets of defendants will not provide substantive redlines because they do not believe they should be subject to any discovery pending Judge Kugler's final motion to dismiss order, Plaintiffs' forthcoming amended complaints, and any challenges to those amended complaints. For the reasons discussed below, this is improper and completely inconsistent with the practice in this litigation.

By way of background for Your Honor, early in this litigation, multiple defendants sought a stay of discovery pending motions to dismiss practice. Judge Kugler flatly denied those requests each time. Subsequently, Magistrate Judge Schneider set a practice whereby parties exchange draft discovery requests; meet and confer about those requests; and then submit proposed requests and any lingering disputes to Judge Schneider for resolution. Magistrate Judge Schneider believed this was a more efficient way to proceed then for defendants to propound "boilerplate" objections in response to discovery requests.

Plaintiffs followed this approach with the Manufacturer Defendants in late 2019. Ultimately, Magistrate Judge Schneider resolved lingering disputes with Plaintiffs' document requests to Manufacturer Defendants and entered court-approved requests to Manufacturer Defendants. *See* 12/23/2019 Order (ECF 328).

Plaintiffs then propounded similar written discovery on Wholesaler and Retail Pharmacy Defendants. But these defendants balked, arguing that they were less critical defendants and should not be subject, at least initially, to discovery as extensive as that directed to Manufacturer Defendants. *See* 12/17/2019 Ltr. from S. Johnston to M.J. Schneider (ECF 323). Magistrate Judge

Schneider suggested Plaintiffs' first round of written discovery to these defendants be less extensive (e.g., no custodial productions, etc.). Plaintiffs acquiesced with the understanding that additional discovery aimed at these defendants would occur at a later phase.

Protracted negotiations ensured over first set of document requests to Wholesaler and Retail Pharmacy Defendants. The process was strung out for months. Ultimately, after extensive argument and briefing, Magistrate Judge Schneider entered court-approved sets of document requests to Wholesaler and Retail Pharmacy Defendants. *See* 07/10/2020 Order (ECF 509). As Your Honor will notice, these requests are significantly pared down from typical requests in a litigation of this kind; e.g., the requests essentially sought production of data, exemplar transactional documents, and a couple of final written policies. *Id.* Large swathes of discoverable topics – including *any* custodial discovery, or routine requests such as organizational charts – were excluded. Again, the expectation was these defendants would be subject to further discovery at a later phase.

After some production miscues, Wholesaler and Retail Pharmacy Defendants substantially completed their productions by the late Fall of 2020. By this time, the parties and Magistrate Judge Schneider were in the throes of finalizing the parameters for Plaintiffs' imminent depositions of Manufacturer Defendants' witnesses. With all of the first phase discovery work behind, on December 8, 2020, Plaintiffs served Wholesaler and Retail Pharmacy Defendants with draft second sets of document requests and deposition notices. *See* Ex. X hereto (cover emails with attachments). Notably, even these requests are substantially narrower than requests to Manufacturer Defendants. Also at this time, there was acute urgency because Judge Kugler had just set an April 1, 2021 deadlines for the completion of *all* discovery.

Plaintiffs tried to meet and confer with Wholesaler and Retail Pharmacy Defendants about this draft discovery, but defendants never responded. Accordingly, with just three months left in discovery, Plaintiffs told Magistrate Judge Schneider this and asked him to enter Plaintiffs' draft discovery request and notices. *See* 12/21/2020 Pls.' Ltr. to Court (ECF 685). These defendants balked, accusing Plaintiffs of misrepresentations and professing their willingness to substantively meet and confer. *See* 12/22/2020 Def. Ltr. to Court (ECF 689). At the December 22, 2020 CMC conference, the parties jointly discussed a proposed amendment to the schedule (specifically, the then-operative April 1 discovery deadline) that would see additional "phase 2" discovery after April 1 include additional discovery directed to Wholesaler and Retail Pharmacy Defendants (called "downstream defendants"):

> [MR. GOLDBERG]: Your Honor, this is Seth Goldberg on behalf of the defendants, and I'll invite plaintiffs' counsel to chime in on this, but the parties have been talking over the past week or so about this schedule that the Court has entered, and what the parties are -- have on their plate in terms of completing between now and April 1, with respect to party depositions, the employees, and the defendants' class representatives and some of the personal injury plaintiffs, and have discussed possibly modifying the schedule to some degree that would keep intact the deadlines the Court has set with respect to general causation issues.
>
> Fact discovery as to general causation issues being completed by April 1, so that the parties can meet the Court's deadlines with respect to general causation Daubert issues, in May through November, which is set forth in CMO 22. ***And moving some of the discovery pertaining to third party -- third parties and downstream defendants beyond April 1, and basically trying to have a period of discovery that would focus on the general causation issues between now and April 1, and then the third-party issues and downstream defendants April 1 to August 1***, and we've also been discussing adding to the schedule a period of class certification briefing to come at the end of 2021 and into 2022.

12/22/2020 Tr. at 73-74 (emphasis added). While Plaintiffs conceptually agreed that additional discovery of Wholesaler and Retail Pharmacy Defendants would not actually occur until "phase 2" – i.e., after April 1 – Plaintiffs explicitly told defendants they wanted the draft discovery resolved prior to April 1, so the three months prior to April 1 were not lost.

In January and February 2021, Plaintiffs had a couple of meet and confer calls with Wholesaler and Retail Pharmacy Defendants. Eventually, Plaintiffs asked each group to provide substantive redlines to Plaintiffs' draft document requests and deposition notices, so any lingering issues could be presented to Your Honor, resolved, and entered by order (as has been the practice with all other written discovery in this litigation).

Neither set of defendants provided substantive redlines. On February 19, 2021, Plaintiffs asked Wholesaler Defendants again for substantive redlines. On February 25, Wholesaler Defendants responded they would not be providing any substantive redlines. Wholesaler Defendants further stated they not only should not be subject to any additional discovery until the Court's final motion to dismiss ruling and the resolution of any challenges to Plaintiffs' anticipated amended complaints, but that they would not even further discuss Plaintiffs' draft discovery until then. *See* Ex. Y (email exchange between Plaintiffs and Wholesaler Defendants). Plaintiffs responded the same day, pointing out that Judge Kugler and Magistrate Judger Schneider had never stayed any discovery in this litigation pending motions practice. Plaintiffs also pointed out that, back in December 2020, the downstream defendants accused Plaintiffs of bad faith in suggesting that these defendants would not substantively meet and confer on this draft discovery, but then here we were months later, and these defendants had yet to provide substantive redlines and were claiming they should be immune to further discovery until a later time. *Id.*

The Retail Pharmacy Defendants responded similarly. They claimed they would not provide any substantive redlines to Plaintiffs' draft discovery. More specifically, they sought an actual or constructive stay of discovery, stating: "we do not think it is appropriate to negotiate additional discovery from the Pharmacy Defendants while the parties and claims in this case are in flux." *See* Ex. Z (2/16/2020 Retail Pharmacy Defs.' Ltr. to Plaintiffs). On February 22, Plaintiffs told Retail Pharmacy Defendants, as they told Wholesaler Defendants, that there is no stay of discovery; the Court has never stayed discovery; and the parties jointly told Judge Kugler that the discovery extension he had granted was to allow "phase 2" discovery – which explicitly included by Wholesaler and Retail Pharmacy Defendants – to occur April 1 to August 1. *See* Ex. AA (email chain between Plaintiffs and Retail Pharmacy Defendants). Retail Pharmacy Defendants replied to reiterate that the Pharmacies are of the view that it does not make sense to negotiate additional discovery with Plaintiffs currently, while the pleadings are in flux[.]" *Id.*

So, as things currently stand, both Wholesaler and Retail Pharmacy Defendants refuse to substantively engage in exchanges of redlines to Plaintiffs' draft discovery, and in fact believe they should not have to engage in any discovery until Judge Kugler issues the in final motion to dismiss order; Plaintiffs file amended complaints; defendants challenge those amendments; and Judge Kugler resolves those challenges. This is flatly inconsistent with the past practice in this litigation, and the parties' explicit statements to the Court that "phase 2" discovery (i.e., April 1 – August 1, 2021) *would* include discovery of Wholesaler and Retail Pharmacy Defendants. Given their new positions' inconsistency with the Court's ruling and practice, these Defendants should have moved for a protective order and placed the issue squarely before the Court rather than simply refusing to answer discovery.

Had Plaintiffs served their requests and notices formally on December 8, 2020, per the Federal Rules of Civil Procedure, instead of faithfully following the Court's practice of having the Parties negotiate draft requests in advance, which Defendants refused to do, the answers to discovery would be well over do at this point. Simply put, three months after Plaintiffs served draft requests and notices, those requests and notices are no closer to being finalized and responded to. Accordingly, The Court should order that these Defendants prepare redlines as to Plaintiffs' discovery requests by March 12, set a schedule for the parties to meet and confer a final time on Plaintiffs' draft requests and notices; and for those drafts and any disagreements to be presented to the Court for resolution at the next CMC.

10. Bellwether Discovery from Defendants

The Fact Sheets for Pharmacy, Wholesaler, API Manufacturer, and Finished Dose Manufacturer Defendants were approved on August 6, 2020. MDL Text Order Dkt. 532 (Ex. BB hereto). The Defense Fact Sheet ("DFS") trigger date for responses 20 individual personal injury Plaintiff Fact Sheets was August 31, 2020. MDL Text Order Dkt. 532. This order required the DFS to be answered in accordance with MDL Text Order Dkt. 532, which describes the initial trigger date as well as Dkt. 452. requiring subsequent DFS responses "60 days after the foregoing response deadline."

During the Bellwether selection process, the parties discussed the importance of having completed defense fact sheets in-hand before Plaintiff depositions and agreed that the remaining DFS deadlines would be halted for the 20 cases originally identified in August but who were not selected by either side for bellwethers. There are 10 cases from that original group of 20 that remain in the agreed upon Bellwether pool.

To date, no Finished Dose Manufacturer or API Manufacturer DFS have been received for any of the 10 cases identified in August 2020. Additionally, Defendants have failed to provide responses at any level of the Defense Fact Sheet in 4 of those 10 cases, as follows:

Bambi Ganim, 1:20-cv-07523,
Yolanda Bonmon, 1:20-cv-09207
Richard Ramirez, 1:20-cv-05595
Estate of Gatson Roberts 1:20-cv-00946

The response that Defendants have offered for not starting the DFS process for the above four cases back on August 6, 2020, is that no defendant retailers were named in these cases. Thus, rather than moving to the wholesaler level of the DFS, the Defendants did nothing.

Further, it appears that in some cases, Defendants have also recently raised unimportant 'Core Deficiencies' for the first time in violation of CMO 16. Yolanda Bonmon, who has yet to receive any level of the DFS, did receive an additional deficiency identified more than 4 months after the 21-day deficiency deadline described in CMO 16 lapsed. These "new deficiencies" have been present since the filing of her original Plaintiff Fact Sheet in August 2020, but were first raised in February 2021.

Further to this point, Defendants indicated in February 2021 that they would not serve a DFS for an additional 7 of the remaining 18 Bellwether pool plaintiffs. At Plaintiff leadership's request, Defendants provided this list of plaintiff fact sheets identified as not substantially complete for the purposes of completing a DFS. This list included multiple Bellwether cases where the only deficiencies was responded to more than 5 months ago, and no further concerns for these 'Core Deficiencies' were raised to plaintiff or the court. For example, Defendant's list included, Maxine Guillory, who served her PFS on August 20, 2020 and to date has not received a deficiency notice through Centrality from the Defense in accordance with CMO 16. Without a specific

deficiency, Ms. Guillory can only guess why Defendants believe her PFS is not substantially complete.

Plaintiffs have requested that defendants re-evaluate all of these 'Core Deficiencies' raised for the 28 bellwether cases, both in light of the timelines set by CMO 16 and in light of the scope of the deficiency itself (whether that information is truly needed for Defendants to complete Defense Fact Sheets).

Respectfully,

ADAM M. SLATER

cc: All Counsel (via CM/ECF)